SIDLEY AUSTIN BROWN & WOOD LLP
1501 K STREET, NW - WASHINGTON, D.C. 20005 - TEL. (202) 736-8000 - FAX (202) 736-8711

FAX TRANSMISSION

Total [23] pages, including cover sheet

To: Commissioner for Patents
U.S. Patent and Trademark Office

Fax no.: (703) 872-9306

From: Tel. (202) 736-8000

Date: March 18, 2005

Re:

Serial No.:	10/015,967	Group Art Unit:	1646
Confirmation No.:	9428	Examiner:	Dong Jiang
Filed:	December 7, 2001		
Applicant:	EATON, et al.		

For: Interlukin-8 Homologous Polypeptides and Uses Thereof

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. § 1.8

I CERTIFY THAT THE FOLLOWING DOCUMENTS ARE BEING TRANSMITTED TO THE USPTO AT FAX NUMBER (703) 872-9306 ON THE DATE SHOWN:

Chianti M. Lloyd
SIGNATURE

Chianti M. Lloyd
PRINTED NAME

March 18, 2005
DATE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

APPEAL BRIEF FOR THE APPELLANT

In re Application of: Eaton et al.	Group Art Unit: 1646
Serial No.: 10/015,967	Examiner: Jiang, Dong
Filed: December 7, 2001	
For: Interlukin-8 Homologous Polypeptides and Uses Thereof	

The Appellant believes that this brief is timely filed, with the attached one-month extension of time. A four-month extension of time was previously submitted with the Amendment filed February 15, 2005. Any fees required in filing this brief, including the fee for extension of time, can be deducted from deposit account No. 18-1260.

The following information and arguments are provided pursuant to 37 C.F.R. § 1.192(c)

(1) Real Party in Interest

The real party in interest in the appeal is:

Genentech, Inc.

1 DNA Way

South San Francisco, CA 94080

(2) Related Appeals and Interferences

The appellant is not aware of any appeals or interferences that will directly affect or will be directly affected by or have a bearing on the Board's decision in this appeal.

Appeal Brief
In re Eaton et al.
Serial No: 10/015,967
Filing Date: 12/07/2001

(3) Status of Claims

Claims 33 to 39 and 41 to 43 are currently pending in the application and stand finally rejected. Claims 1 to 32 and claim 40 have been canceled. Claims 33 to 39 and 41 to 43 are presently under appeal. A copy of the currently pending/appealed claims are provided in the attached Appendix.

(4) Status of Amendments

There are no pending amendments. Note, the Appellant filed an amendment after final on February 15, 2005 to put the claims in better condition for appeal, which the examiner entered. See Advisory Action Before Appeal Brief—a courtesy copy of which was faxed to the Appellant prior to its official mailing date.

(5) Summary of Invention

The invention relates to novel isolated polypeptides having structural homology to the chemokine interleukin-8. The invention further relates to isolated polypeptides with 80, 85, 90, 95 and 99 percent identity to the polypeptide of SEQ ID NO:2 or ATCC accession number 203004 and chimeric polypeptides that chemoattract monocytes and dendritic cells. At least the following sections in the specification identify the invention:

- Page 11, line 28 to page 12, line 21, discussing polypeptide embodiments of the invention;
- Page 13, lines 28 to 31, discussing chimeric molecules of the present invention;
- Page 47, line 12 to page 52, line 7, discussing the polypeptide, including variants, fragments and chimeras thereof, of the present invention;
- Figure 2 showing the amino acid sequence (SEQ ID NO:2) of the present invention;
- Figures 6, 7, and 8 showing the chemoattracting activity of the polypeptides of the invention;

- Examples 2, 3, 4 and 5 discussing the expression of the polypeptides of the invention;
- Example 10 discussing microarray analysis to detect overexpression of the polypeptides of the invention in cancerous tumors;
- Example 12, discussing threading analysis of the polypeptides of the invention to determine homology to known polypeptides; and
- Example 13, discussing the chemoattracting activity of the polypeptides of the invention.

(6) Issues

(a) Whether the present application (U.S.S.N. 10/015,967) is entitled to priority under §120 to international application PCT/US00/23328, filed 8/24/00, thereby rendering the Lal reference not prior art under § 102(b).

(b) Whether claims 33 to 39 and 41 to 42 are unpatentable in view over Lal (WO 200000610-A2), under §102(e) or §102(b), as the case may be in view of issue (a); and

(c) Whether claim 43 is unpatentable under 35 U.S.C.§ 103(a) over Lal, in view of Capon, et al. (U.S. Patent No. 5,116,964).

Appeal Brief
In re Eaton et al.
Serial No: 10/015,967
Filing Date: 12/07/2001

(7) **Grouping of Claims**

All pending claims (33 to 39, 41 to 42 and 43) stand or fall together. While claim 43 is not subject to the § 102(b) rejection over Lal, the 103(a) rejection of that claim is based on Lal reference.

(8) **Arguments**

(i / ii) **There are no 112 rejections.**

(iii) **Rejection of claims 33 to 39 and 41 to 42 under 35 U.S.C. §102(b) as being anticipated by Lal, et al., WO 200000610-A2 ("Lal"). Additionally, the rejection of claim 43 under § 103(a) in light of the Lal.**

(1) **Summary of the rejection**

The Examiner has rejected claims 33 to 39 and 41 to 42 under 35 U.S.C. § 102(b) as being anticipated by Lal et al., WO 200000610-A2 ("Lal"). The Examiner asserts that Lal "discloses a polypeptide, a human signal peptide-containing protein having an amino acid sequence of SEQ ID NO:94, which is 100% identical to SEQ ID NO:2 of the instant invention." The Examiner also asserts that Lal teaches that SEQ ID NO:94 is a signal peptide-containing protein, indicating that it is a mature protein lacking the signal peptide, and therefore Lal anticipates claim 40. Finally, the Examiner asserts that Lal teaches a fusion protein comprising the polypeptide and a heterologous moiety and therefore Lal anticipates claim 42.

The Examiner's position appears to be that the mere disclosure of the sequence of a polypeptide is sufficient to anticipate under §102(b). Thus, the Examiner takes the view that the failure of Lal to disclose any information regarding any characteristics of the polypeptide sequence, such as its biological role, function or activity, and the failure to identify any specific, substantial or credible utility for the polypeptide, the Lal disclosure fulfills the requirements for anticipation of the present claims under 35 U.S.C. § 102(b).

Claim 43 stands rejected under 35 U.S.C.§ 103(a) over Lal, et al in view of Capon (U.S. Patent No. 5,116,964). For this rejection, the Examiner asserts that Capon discloses a novel polypeptide comprising an immunoglobulin Fc region and a target protein sequence for use, among other things, to extend the *in vivo* half-life of the resulting fusion protein. The Examiner further asserts that one of ordinary skill in the art would have been motivated to use the polypeptide disclosed in Lal to make a fusion protein as taught by Capon in order to, for example, facilitate protein purification.

(2) Appellant's Priority Claim to various earlier-filed applications

Appellant's current application, 10/015,967 ("the '967 application"), claims priority to various earlier filed applications under §§ 119 and 120.[1] In particular, the current application claims priority to international application PCT/US00/23328, filed on 8/24/00. The Examiner refused to give the '967 application the benefit of priority under § 119 and 120 to any of the earlier-filed applications citing deficiencies under §§ 101 and 112. See Office Action dated 6/6/03. According to the Examiner, the effective filing date of the '967 application is 12/7/01.

Appellant argued during prosecution, that the present application is entitled to at least the benefit of international application PCT/US00/23328 ("the '328 application), filed 8/24/2000. However, the Examiner disagreed with the Appellant's argument and denied a claim of priority to the '328 application. According to the Examiner, the data provided in the '328 application apparently failed to provide support under § 101 for a diagnostic utility for three reasons. *See* Office Action dated 4/6/2004, page 3.

Appellant submits that the Examiner has erroneously refused to recognize Appellant's claims for benefit and priority. Contrary to the Examiner's assertions that the Appellants

[1] The present application claims priority under §§ 119 and 120 to U.S.S.N. 60, 090,696 filed 6/25/98, PCT/US99/12252, filed 6/2/99, U.S.S.N. 09/380,137, filed 8/25/99, PCT US00/23328, filed 8/24/00, U.S.S.N 09/709,238, filed 11/8/00, PCT/US01/06520, filed 2/28/01, U.S.S.N.

"provide no guidance or working examples to teach how to use the claimed invention," the '328 application does provide guidance to one skilled in the art that supports several substantial and specific utilities recited for the claimed polypeptides. For example, the '328 application discloses that the claimed polypeptides are differentially expressed in diseased tissue as compared to a normal tissue of the same type. *See* p. 62, lines 34-37. Example 18 (p. 93 of the '328 application) shows that the polynucleotide encoding SEQ ID NO:2 is differentially expressed in normal esophagus versus esophageal tumor tissue and rectum tumor tissue relative to normal rectum tissue.

Those who work in the cancer field are aware that in the vast majority of cases, when a gene is over-expressed, as evidenced by an increased production of mRNA, the gene product or polypeptide will also be over-expressed. It is unlikely that one identifies increased mRNA expression without associated increased protein expression. Stated another way, two cell samples which have differing mRNA concentrations for a specific gene are expected to have correspondingly different concentrations of protein for that gene. Techniques used to detect mRNA, such as Northern Blotting, Differential Display, *in situ* hybridization, quantitative PCR, Taqman, and more recently Microarray technology all rely on the well-accepted theory that a change in mRNA will represent a similar change in protein. If this theory did not hold true then these techniques would have little value and not be so widely used. The use of mRNA quantitation techniques have identified a seemingly endless number of genes which are differentially expressed in various tissues and these genes have subsequently been shown to have correspondingly similar changes in their protein levels. Thus, the detection of increased mRNA expression is expected to result in increased polypeptide expression. The detection of increased polypeptide expression can be used for cancer diagnostic and treatment.

However, even in the case where the protein expression does not correlate with the mRNA expression, this still provides significant information useful for cancer diagnosis and

---

09/941,992, filed 8/28/01, and PCT/US00/08439, filed 3/30/00.

treatment. For example, if over-expression of a gene product does not correlate with over-expression of mRNA in certain tumor types but does so in others, then identification of both gene expression and protein expression enables more accurate tumor classification and hence better determination of suitable therapy. In addition, absence of over-expression of the gene product in the presence of a particular over-expression of mRNA is crucial information for the practicing clinician. If a gene is over-expressed, the clinician accordingly will decide not to treat a patient with agents that target that gene product.

Appellant believes that the above-cited evidence and argument demonstrates that the polypeptides of the current invention are useful diagnostically or therapeutically for the determination of the presence or absence of at least esophageal and rectal tumors in a subject suspected of possessing such tumors. As such, the Appellant has demonstrated at least one specific, substantial and credible utility – in particular, a diagnostic application – for the claimed inventions of the present application. The claimed invention is entitled, pursuant to 35 U.S.C. §120, to at least the filing date of the applications that provide this evidence of utility, which include at least the '328 application (i.e., providing a filing date for the application of at least as early as 8/24/2000).

(3) Appellant's observations on the scientific credibility and content of the Lal disclosure

Importantly, the Examiner has not contested Appellant's observed deficiencies of the Lal disclosure, which are numerous and include the following:

- A majority of the disclosure is generic to the 134 molecules disclosed in the publication

  Lal discloses a total of 134 human signal peptide-containing proteins (collectively referred to in Lal et al., and hereinafter as "HSPP") and their corresponding nucleotide sequences, but provides nothing more than non-specific recitations regarding the potential use of those polypeptide sequences. For example, Lal et al., contains the following statements—none of which are specific to the polypeptide of

SEQ ID NO: 94—regarding possible grounds to support utility of the 134 disclosed polypeptides:

- ...the expression of HSPP is closely associated with proliferative, cancerous, inflamed, cardiovascular, nervous, reproductive, hematopoietic/immune, and development tissue. Therefore, HSPP appears to play a role in cell proliferation disorders including cancer; inflammation; and cardiovascular, neurological, reproductive, and developmental disorders. Page 40, lines 10-15.
- In the treatment of cell proliferative disorders...associated with increased HSPP expression or activity, it is desirable to decrease the expression or activity of HSPP. Page 4, lines 15-18.
- In the treatment of ...conditions associated with decreased HSPP expression or activity, it is desirable to increase the expression or activity of HSPP.
- Lal goes on to list approximately 300 diseases or conditions that may possibly be treated by increasing HSPP expression or activity. Page 40, line 18 – page 43, line 6. If anything, the recitation of such a laundry list of varied and biologically diverse conditions would suggest that Lal et al. in fact had no idea what the HSPP of SEQ ID NO:94 could be used for.

Appellant submits that none of the above-recited disclosures is sufficient to provide a specific or substantial utility for the HSPP polypeptide encoded by SEQ ID NO:94.

- The Northern blot expression data disclosed in Lal for SEQ ID NO:94 provides no guidance to a person of skill in the art to ascertain the biological role, function or activity of the disclosed polypeptide.

It appears that the purported utility for the disclosed HSPP polypeptides is grounded merely on a tissue distribution analysis. However, Lal fails to provide any data that can reasonably establish any biological function of the HSPP of SEQ ID NO:94 that could serve as a basis for an assertion of a specific, substantial and credible utility. In Table 3, Lal provides a description of the tissue distribution patterns of the nucleic acid sequence that encodes the polypeptide of SEQ ID NO:94 as determined by Northern blot analysis. Based on that expression pattern, Lal predicts that expression of the polypeptide of SEQ ID NO:94 will be associated with certain diseases, disorders and conditions. Lal does not disclose, however, any comparisons between expression of this sequence in normal vs. abnormal (e.g., tumor) tissue. For example, according to Table 3 in Lal the HSPP of SEQ ID NO:94 is expressed in cardiovascular, reproductive and urologic tissue. Solely on this basis, Lal predicts that expression of this sequence is implicated in cancer, inflammation and fetal or proliferating diseases or conditions. However, by failing to characterize expression of the sequence in abnormal versus normal tissue, these showings in Lal are meaningless. Simply put, a person of skill in the art would attach no significance to the expression data as presented because no comparisons are made between abnormal and normal tissue.

- Limited structural data disclosed for polypeptide of SEQ ID NO:94 provides no guidance to a person of skill in the art to ascertain the biological role, function or activity of the disclosed polypeptide.

Lal provides no structural homology comparison information for the polypeptide of SEQ ID NO:94. While homology to a known and characterized polypeptide cannot by itself ordinarily provide the basis on which a biological activity can be demonstrated, it can provide one of skill in the art with at least a starting point to conduct further testing regarding a likely activity or function. Lal fails to provide any homology comparison data and as a result, cannot make any homology based predictions regarding the activity or function of SEQ ID NO:94.

> Moreover, Lal also predicts, incorrectly, that the polypeptide of SEQ ID NO:94 contains a transmembrane domain. See Table 2, page 100. It is now known that the polypeptide of SEQ ID NO:94 is not a membrane-bound protein but rather a secreted protein without a transmembrane domain. Accordingly, this physical characterization specific to the polypeptide of SEQ ID NO:94 provided by Lal would be nothing but misleading to one of skill in the art.

Thus, while Lal discloses the predicted amino acid sequence for the HSPP of SEQ ID NO:94, it fails to disclose any information that describes in any credible manner any specific biological role, function or activity associated with the polypeptide. Instead, the disclosure speculates as to possible functions or activities that the class of 134 HSPP polypeptides might possess. Even in this respect, the Lal disclosure makes these representations in a way that is so generalized and abstract as to be meaningless to a person of ordinary skill in the art. The Lal disclosure provides no data or information that can reasonably establish any biological function or activity of the HSPP of SEQ ID NO:94, much less information that could establish a specific role of the polypeptide. The attempt by Lal to predict possible utilities for the polypeptide on incomplete physical characterization of the molecule and insufficient tissue distribution data fails to provide one of skill in the art with any meaningful information regarding a specific, substantial or credible utility for the currently claimed polypeptide.

The Examiner has not contested the observations put forward by the Appellant regarding the scientific deficiencies of the Lal disclosure. Instead, the Examiner has maintained that these deficiencies in Lal do not affect its status as an anticipatory prior art reference under 35 U.S.C. §102(b). In particular, the Examiner has stated that "the statute of 102(b) itself merely requires that 'the invention was patented or described in...' the prior art (emphasis in original). And because Lal discloses the polypeptide sequence of the present invention, "the present invention has been well described by the prior art reference and the prior art reference meets the anticipating requirement of 102(b) [emphasis added]." See 04/06/04 Office Action at p. 6. In the subsequent Advisory Action dated 09/21/04, the Examiner further stated that "whether the Lal reference provides any information regarding biological role, function or activity of the polypeptide is irrelevant with respect to the rejection, and it does not affect the reference being anticipating art for the rejection of the present claims under 35 U.S.C. 102(b)." The Examiner cited no case law to support these positions.

(3) Lal is legally insufficient to anticipate the presented claims

A. *Priority Claim*

The Board should find that the present application is entitled to the filing date of at least the '328 application under § 120. As such, the Lal reference was published less than one year after the filing date of the present application, and cannot support a rejection of the claims under § 102(b). In such case, Lal could only be used, at most, to reject the claims under § 102(e).

Appellant submits that Lal cannot anticipate the present claims under the standards that govern anticipation under §102(e). Appellant submits that the proper standard is that articulated by the Court of Customs and Patent Appeals in *In re Wertheim and Mishkin*, 209 USPQ 554 (CCPA 1981); namely, that an international publication can anticipate under 35 U.S.C. § 102(e) as of a particular date only to the extent that there is a sufficient disclosure under 35 U.S.C. § 112, first paragraph, for the subject matter at issue (i.e., the subject matter of the claims being rejected as being anticipated under §102(e) by the patent). As explained below, Appellant submits that Lal does not support the present claimed subject matter under § 112, and therefore, cannot be a proper § 102(e) reference.

The conceptual justification for giving a U.S. patent prior art status earlier than the date that the contents of the patent become public was first articulated in *Alexander Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390, 401 (1926).[2] There, the Supreme Court reasoned that a patent owner should not be penalized for the administrative delays associated with examining and granting patents. According to *Alexander*, if a patent application could issue *claiming the subject matter at issue* on the same date it was filed—but for PTO prosecution delays—it should have prior art effect as from the date of its filing. *Id.* at 401. The critical point was that a patent could issue on the subject matter at issue.[3] Thus, under Alexander, the prior art effect of a patent

---

[2] Section 102(e) was added to the patent statue as a result of the Alexander decision *See, e.g.*, Commentary on the New Patent Act, P.J. Federico, Vol. 75, No. 3, page 179, J. Pat.

[3] The Court in *Alexander* also held that "[i]t is not disputed that this [102(e)] application gave a complete and adequate description of the thing patented to Whitford, but it did not claim it." *Id* at 399; "Delays in the patent office ought not to cut down the effect of what has been done. The description [in the 102(e) reference] shows that Whitford was not the first inventor." *Id.* at 401.

disclosure is limited to that subject matter in the patent disclosure which could support a claim as required by, *inter alia,* 35 U.S.C. 112, first paragraph.[4]

In *Wertheim*, the court addressed the specific question of the effective date – for prior art purposes – to be given to a patent under 35 U.S.C. §§102(e)/103 where the patent claimed the benefit of an earlier application under 35 U.S.C. §120. The court held that the §102(e) effective date of the patent was limited to that subject matter in the patent that could satisfy the requirements of 35 U.S.C. § 112, first paragraph, relative to the claims being rejected.[5] Thus, the court recognized that a patent should be entitled to a prior art effect under § 102(e) *only as to subject matter that was disclosed in a manner that would be sufficient under § 112, first paragraph.*[6] While the specific question at issue in *Wertheim* concerned the sufficiency under § 112 of an earlier filed application to which the patent claimed priority under § 120, the logic of *Wertheim* applies with equal force to patents and, in this case, international publications that do not make such priority claims.

Specifically, in *Wertheim*, the court held that in order for the patent to enjoy prior art status under § 102(e), the application to which priority is claimed must satisfy the disclosure

---

[4] *See also, In re Bayer,* 568 F.2d 1357 at 1361, where the CCPA in discussing the difference between § 102(e) and § 102(b) stated:

> The concept underlying 35 U.S.C. § 102(e) is that a complete description of an applicant's invention in an earlier filed application of another, which subsequently matures into a patent, constitutes prima facie evidence that the applicant is not the first inventor of the invention in controversy. The Supreme Court in [Alexander] Milburn was of the opinion that administrative delays in the patent office should not detract from the anticipatory effect of such evidence."

[5] See, *Wertheim* at 537 ("Thus, the determinative question here is whether the invention claimed in the Pfluger patent finds a supporting disclosure in compliance with §112, as required by §120, in the 1961 Pfluger I application so as to entitle that invention in the Pfluger patent, as "prior art," to the filing date of Pfluger I. Without such support, the invention, and its accompanying disclosure, cannot be regarded as prior art as of that filing date.")

[6] *See Wertheim* at 539 ("... the application, the filing date of which is needed to make a rejection, must disclose, pursuant to §§120/112, the invention claimed in the reference patent.")

requirements of the first paragraph of §112 for the claimed subject matter at issue. *See Wertheim* at 537. It is entirely consistent with the logic of this provision that the *actual* patent disclosure (i.e., the disclosure that is in the application that led to the patent, rather than an earlier application to which a claim under § 120 is made) must meet the requirements of § 112, first paragraph, for the subject matter being rejected.

For the numerous reasons set forth above, the Lal reference does not provide an adequate disclosure under §112, first paragraph of the subject matter of the presently appealed claims. Indeed, applying the PTO's own guidelines concerning compliance with §112, first paragraph clearly shows that Lal cannot support the present claims. As stated above, the absence of any experimental data establishing the role, function or activity of the polypeptide, render the disclosure of Lal incapable of establishing a specific, substantial and credible utility for the polypeptide. As mentioned above, Lal provides limited characterization of the polypeptide and provides no homology data. Moreover, there is no data provided in the Lal disclosure that can reasonably establish any biological function or activity of the HSPP of SEQ ID NO:94, much less information that could establish a specific role of the polypeptide.

Based on substantial precedent (*See, e.g., In re Zeigler, In re Brana, and In re Fouche)*, if the Lal reference fails to satisfy § 101 for the presently claimed subject matter, it fails to meet the requirements of § 112, first paragraph. In particular, the insufficient disclosure in Lal regarding the polypeptide of SEQ ID NO:94 (i.e., the disclosure does not set forth a specific, substantial and credible utility for the polypeptide), makes it impossible for Lal to satisfy the "how to use" prong of § 112 for the presently claimed subject matter. As a matter of law, because Lal fails to satisfy the requirements of § 101, it fails to provide an enabling disclosure under § 112 and cannot anticipate the appealed claims under § 102(e).

B. 102(b) Rejection

As an initial matter, Appellant maintains that the current claims are entitled to a priority date of at least 8/24/2000 as explained above. As such, Lal was published on 1/6/2000, less than one year prior to the Appellant's effective filing date and cannot be prior art under § 102(b). On that basis alone, Appellant respectfully requests the Board to remove the § 102(b) rejection over Lal.

In addition, the Appellant has maintained throughout the examination of this application that the scientifically deficient disclosure of Lal renders it legally insufficient to anticipate the appealed claims. In particular, the Lal disclosure does not provide an accurate or unequivocal characterization of any biological function, activity or role of the HSPP of SEQ ID NO:94. Instead, it merely discloses a polypeptide sequence and speculates – inaccurately and incompletely – as to the biological function, role and activity of the HSPP-class of polypeptides to which the polypeptide of SEQ ID NO:94 apparently belongs.

If priority is not granted to the '238 application, the proper resolution of this appeal turns on determining the proper legal standard for measuring the sufficiency of a prior art reference for anticipation under 35 U.S.C. § 102(b). Appellant submits that the proper standard is that articulated by the Court of Customs and Patent Appeals in *In re LeGrice*, 301 F.2d 929, 936, 133 U.S.P.Q. 365 (C.C.P.A. 1962). According to *LeGrice*, to qualify as prior art under § 102(b), a printed publication must enable those skilled in the art to "understand the nature and operation of the invention and carry it into practical use." Appellant argues that if a printed publication, coupled with the knowledge in the art, fails to identify that subject matter is an "invention" or enable one of skill to carry that invention into practical use (e.g., because it fails to adequately describe or it fails to teach how to use the subject matter), the reference cannot be a bar to patenting under 35 U.S.C. § 102(b).

As set forth above, Lal—in conjunction with the knowledge in the art—does not satisfy the requirements of § 101 and cannot, therefore, constitute an anticipatory reference under § 102(b). Because the polypeptide of SEQ ID NO:94 in the Lal reference had no known use when the Lal reference was filed and the Lal reference provides no specific, substantial and credible use for the polypeptide, Lal did not appreciate that the sequence was in fact an invention, and did not put the polypeptide of SEQ ID NO:94 into "public possession" as contemplated by the patent

law. The idea behind § 102(b) is to preclude patenting of an invention that had previously been dedicated to the public. Appellant contents that no such dedication can take place until *some* specific, substantial and credible utility is known for the invention. Until such time, the public derives no benefit from the invention.

Appellants are aware of various Federal Circuit and CCPA decision that address factual situations similar to the one presented in this Appeal. For example, *In re Schoenwald*[7], *In re Hafner*[8], *In re Samour*[9], *In re Donohue*[10], and *In re Spada*[11] address what, in terms of enablement and utility, a reference must disclose before it can be properly considered § 102(b) prior art. For example, *Schoenwald* and *Spada* clearly stand for the proposition—and rightfully so—that discovering a *new* use for a compound or composition already known in the art to have a use, does not make the compound or composition patentable to the discoverer of the new use. However, Appellant contends that it is improper for the Office to apply this line of cases in situations, such as here, where neither the cited reference nor the knowledge in the art provides any known use for the compound or composition applicant wishes to claim.

(4) The Board Should Address the Important Public Policy Considerations Raised in the Present Appeal

The policies and practices of the Office in examining applications in the field of genomics make it absolutely clear that the sufficiency of disclosure of an application and of cited prior art is a critical inquiry in the examination of these applications.[12] These policies are motivated by the apparent recognition by the Office that the disclosure of sequence information in relation to an invention in the field of genomics can be insufficient, standing alone, to support a claim (under 35 U.S.C. §§ 101 and 112) to a particular nucleic acid, polypeptide or downstream inventions. Indeed, in unpredictable fields of genomics and biotechnology, the

[7] 964 F.2d 1122, 22 USPQ.2d (Fed. Cir. 1992)
[8] 410 F.2d 1403, 161 USPQ 783 (CCPA 1969).
[9] 571 F.2d 559, 197 USPQ 1 (CCPA 1978)
[10] 632 F2d 123, 207 USPQ 196 (CCPA 1980)
[11] 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990)
[12] The Office has promulgated examination guidelines that specifically address the requirements under 35 U.S.C. § 112, first paragraph (written description) and under § 101 for utility, as they pertain to inventions in the field of genomics. *See* 66 Fed. Reg. 1092 (2001).

disclosure of sequence information, without information derived from expression and characterization of a particular polypeptide, provides little if any value from a scientific perspective and certainly does not put the public "in possession" of such sequence as contemplated by § 102(b).

Of particular importance to the present appeal are the Office's requirements of 35 U.S.C. §101 and §112, first paragraph as promulgated in the 2000 Written Description/Utility guidelines. These guidelines were motivated by and have had a clear impact on applications claiming inventions in the field of genomics. The examination guidelines and the training materials associated with those guidelines draw clear lines for applications claiming inventions in the field of genomics. Under any reasonable interpretation of those standards the Lal disclosure is insufficient to support a claim for the presently claimed subject matter under §§ 101 and 112, first paragraph.

However, by giving the Lal disclosure status as prior art under § 102(b), the Office is creating an inherently unworkable legal environment that will adversely effect the biotechnology industry and deprive its downstream beneficiaries of the products of the industry. For example, as in the present case, the Office, by applying Lal as a 102(b) reference will refuse to grant Appellant patent claims concerning the polypeptide despite the fact that the Lal reference cannot support such claims. Thus no party will be granted patent rights in the presently claimed subject matter. In the field of biotechnology and therapeutic development, the absence of effective patent protection will dissuade companies from pursuing development of such inventions. The impact of the Office's policies in this field, thus, can deprive the public of potential new drugs and therapeutic regimens to address unmet medical needs.

The only viable resolution of this dilemma is for the Office to construe the law governing § 102(b) so as to require a reference – when it is cited as prior art under § 102(b) –to support the subject matter defined by the rejected claims in a manner that complies with the requirements of § 112, first paragraph (including, inter alia, the requirements of § 101). Such an interpretation is consistent with the underlying public policy of § 102(b).

(iv) Rejection of claim 43 under 35 U.S.C. §103(a) as being obvious over Lal in view of Capon, et al. (U.S. Patent No. 5,116,964).

Appeal Brief
In re Eaton et al.
Serial No: 10/015,967
Filing Date: 12/07/2001

The Examiner has rejected claim 43 as being obvious in view of Lal taken in view of the '778 patent. While the examiner concedes that Lal fails to disclose a fusion protein of the claimed polypeptide, she asserts that Capon discloses a novel polypeptide comprising an immunoglobulin Fc region and a target protein sequence. The fusion in Capon can be used, among other things, to extend the *in vivo* half-life of the resulting fusion protein. The Examiner further asserts that one of ordinary skill in the art would have been motivated to use the polypeptide disclosed in Lal to make a fusion protein as taught by Capon in order to, for example, facilitate protein purification.

For the reasons presented above, Appellant maintains that Lal is not prior art under 35 U.S.C. §§ 102(b) or (e) to the present claims. As such, Applicants believe a rejection under 35 U.S.C. §103(a) of claim 43 in view of Lal alone or in view of any other reference, is inappropriate.

In addition, Applicants submit that the Capon disclosure fails to provide sufficient motivation or direction to modify the teachings of Lal to arrive at the subject matter of claim 43. The Capon disclosure does not suggest, for example, that polypeptides of the class or having a structure comparable to that of SEQ ID NO:2 could or should be modified in the manner that is claimed. The Capon disclosure similarly fails to provide any motivation for selecting a polypeptide of the nature of that specified in SEQ ID NO:2, given the absence of any description in Lal of the nature or biological characteristics of that polypeptide.

For the above reasons, Applicant respectfully requests the Examiner to withdraw the rejection of claim 43 under § 103(a) based on *Lal et al.*, taken in view of *Capon et al.*.

* * * * * * * * * * * * * * *

Appeal Brief
In re Eaton et al.
Serial No: 10/015,967
Filing Date: 12/07/2001

In view of the points made above regarding the Lal reference, Appellant believes that the pending claims are in condition for allowance and should be passed to issue. Accordingly, Appellant respectfully requests the Office to reverse the rejections of record.

Respectfully submitted,
GENENTECH, INC.

Date: March 18, 2005 By: _____

Jeffrey P. Kushan
Reg. No. 43,401
Telephone No. (202) 736-8914

(9) Appendix: Copy of the Claims Involved in the Appeal

Claims 1-32 (cancelled).

33. (currently amended) An isolated polypeptide that chemoattracts monocytes and dendritic cells and having at least 80% amino acid sequence identity to:

(a) the amino acid sequence of the polypeptide of SEQ ID NO:2; or

(b) the amino acid sequence of the polypeptide encoded by the full-length coding sequence of the cDNA deposited under ATCC accession number 203004.

34. (previously presented) The isolated polypeptide of Claim 33 having at least 85% amino acid sequence identity to:

(a) the amino acid sequence of the polypeptide of SEQ ID NO:2; or

(b) the amino acid sequence of the polypeptide encoded by the full-length coding sequence of the cDNA deposited under ATCC accession number 203004.

35. (previously presented) The isolated polypeptide of Claim 33 having at least 90% amino acid sequence identity to:

(a) the amino acid sequence of the polypeptide of SEQ ID NO:2; or

(b) the amino acid sequence of the polypeptide encoded by the full-length coding sequence of the cDNA deposited under ATCC accession number 203004.

36. (previously presented) The isolated polypeptide of Claim 33 having at least 95% amino acid sequence identity to:

(a) the amino acid sequence of the polypeptide of SEQ ID NO:2; or

(b) the amino acid sequence of the polypeptide encoded by the full-length coding sequence of the cDNA deposited under ATCC accession number 203004

37. (previously presented) The isolated polypeptide of Claim 33 having at least 99% amino acid sequence identity to:

(a) the amino acid sequence of the polypeptide of SEQ ID NO:2; or

(b) the amino acid sequence of the polypeptide encoded by the full-length coding sequence of the cDNA deposited under ATCC accession number 203004.

38. (previously presented) An isolated polypeptide comprising:

(a) the amino acid sequence of the polypeptide of SEQ ID NO:2; or

(b) the amino acid sequence of the polypeptide encoded by the full-length coding sequence of the cDNA deposited under ATCC accession number 203004.

39. (previously presented) The isolated polypeptide of Claim 38 comprising the amino acid sequence of the polypeptide of SEQ ID NO:2.

40. (Cancelled)

41. (previously presented) The isolated polypeptide of Claim 38 comprising the amino acid sequence of the polypeptide encoded by the full-length coding sequence of the cDNA deposited under ATCC accession number 203004.

42. (previously presented) A chimeric polypeptide comprising a polypeptide according to Claim 33 fused to a heterologous polypeptide.

43. (previously presented) The chimeric polypeptide of Claim 42, wherein said heterologous polypeptide is an epitope tag or an Fc region of an immunoglobulin.